Appl. No : 10/669,238 TC/A.U.: 1761

Applicant : Creighton et al. Examiner : T. Tran Lien

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Title : High Fiber High Protein Ready-To-Eat Cereal

Commissioner for Patents Mail Stop AF PO Box 1450 Alexandria, VA 22313-1450

## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

This paper is filed in response to the Advisory Action dated June 16, 2006, accompanies a notice of appeal, and is provided with connection with a request for a preappeal brief review of the rejections presented in the above-identified U.S. patent application.

The present invention addresses problems with dry, short lived, highly frangible features of high insoluble fiber products, gummy or slimy consumption features of high soluble fiber products, and decreased starchy constituents in connection with at least high protein products in arriving at a high insoluble fiber, high soluble fiber and high protein ingredient cooked dough product that has superior organoleptic attributes or qualities. Specifically, claim 1 requires a cooked cereal dough product to have 5-15% total insoluble fiber content, 5-15% total soluble fiber content wherein the weight ratio of total insoluble to total soluble fiber ranges from about 1:1 to 1.5:1, and 15-30% total protein content from a plant protein ingredient. Method claim 30 has corresponding limitations, along with a drying step to achieve dried cereal dough pieces having a water activity of about 0.1 to 0.3.

In an Advisory Action issued on June 16, 2006, the Examiner agreed to enter an amendment after final to claim 45 to overcome a formal rejection but maintained her position regarding the prior art rejections. Thus, claims 1-11, 14-25, 28-30, 37, 38 and 43-48 currently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ringe in view of Sander. Claims 12, 13, 26, 27, 31-36 and 39-42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ringe in view of Sander and further in view of Van Lengerich et al. In essence, the Examiner argues that the claims presented in the present application simply combine known ingredients in the art without producing any unexpected results. Thus, having found references which teach the individual ingredients presented in the claims, the Examiner holds that it would have been obvious to one of ordinary skill in the art to combine the ingredients in the specified ranges and ratios to make the specifically claimed cereal product. It is submitted that these rejections are clearly erroneous for at least the reasons set forth below.

Initially, the Applicant respectfully submits that the Examiner has improperly shifted the burden of proof onto the Applicant to prove unexpected results obtained by the combination of ingredients presented in accordance with the present invention without initially establishing a prima facie case of obviousness. That is, if the Applicant cannot show unexpected results when combining known ingredients, any such combination is held as obvious. Therefore, the Examiner is simply combining references in the prior art, each of which contain individual ingredients that are present in the covered product set forth in the claims of the present application, without any motivation to combine the ingredients in the manner suggested other than a broad perfunctory statement that it is obvious to one of skill in the art to add, for example, a high amount of protein to the Ringe cereal product when desiring a product having a high fiber and protein content. The Examiner goes on to state, in responding to a question of motivation to add any protein to Ringe, that adding an ingredient for its known purpose would have been obvious to one of ordinary skill in the art. This position is not supported by existing case law. For example, the U.S. Courts of Customs and Patent Appeals stated in In re Sponnoble that a patentable invention, within the ambit of 35 U.S.C. § 103, may result even if the inventor has, in effect, merely combined features, old in the art, for their

known purpose, without producing anything beyond the results inherent in their use. (*In re Sponnable* 56 CCPA 823) (emphasis added). The fact remains that the <u>art</u> must provide the proper motivation for the combination, rather than the combination being just considered obvious by the Examiner, who is well beyond one of ordinary skill in the art, without any teaching to make the combination.

The Applicant submits that the Examiner clearly recognizes the deficiencies in Ringe, at least with respect to the inclusion of any protein ingredient, the timing of adding protein, the amount of protein included, the particle size of the fiber, the puff frying and the addition of a high potency sweetener. To address deficiencies, the Examiner cites Sander, which is directed to a high protein cereal, and holds that it would be obvious of one of ordinary skill in the art to add the high protein ingredients of Sander to Ringe. But why? Simply because Sander discloses a high protein cereal does not motivate one to make Ringe both a high fiber and a high protein cereal. And why a high fiber/high protein cereal with the specified insoluble to soluble fiber ranges? Why the specified timing of adding the protein, the specified fiber particle size and other particularly features of dependent claims? Proper teachings and motivation are simply lacking to render these inventive aspects unpatentable.

Certainly, the test for patentability under 35 U.S.C. §103 is basically whether the differences between the claimed subject matter, considered as the whole, and the prior art would have been obvious at the time the invention was made. *Graham v. John Deere Co.*, 381 U.S. 1, 148 USPQ 459 (1966). A proper rejection under 35 U.S.C. §103 cannot be based on hindsight knowledge of the invention under consideration for the sole basis of attempting to meet the recitations of the claims. Specifically, the CAFC in *Environmental Designs, Ltd. v. Union Oil Co. of Cal.* 218 USPQ 865, 870 (1983) stated:

All the pieces of the present invention were known in the art,... That all elements of an invention may have been old (the normal situation), or some old and some new, or all new, is, however, simply irrelevant (emphasis added). Virtually all inventions are combinations and virtually all are combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art (Case citations).

In the art of food sciences, there is a set list of ingredients approved by the FDA for human consumption. All food products must contain one or more ingredients from that list. In short, inventors are limited to a defined list of ingredients that may be combined to produce new or novel food products. In the present situation, cereal products with insoluble fiber and soluble fiber ingredients are known. In addition, a cereal with a protein ingredient is known. All of these ingredients are on the list of FDA approved ingredients. However, this just indicates that pieces of the present invention are known which, in considering patentability of the invention, is simply irrelevant. None of the prior art discloses or suggests the combination of the multiple forms of fiber and the plant protein ingredient presented in the specific ranges claimed. The Examiner holding that the combination is obvious just because the main ingredients of the invention are known is simply improper. As set forth above, the courts have already ruled against taking such a position. Moreover, if a manufacturer wishes to produce a product that will meet with FDA approval, all of the ingredients found in the product must be FDA approve, i.e., the ingredient must come from the defined list of FDA approved ingredients. That is, all existing FDA approved food items are combinations of known ingredients. It is the particular combination, processing and final product that form the invention. If the Examiner is permitted to combine any combination of ingredients in any ranges or percentages simply because they exist and could be so combined, food product manufacturers will, effectively, be prevented from patenting any new products.

The CAFC in *In re Gordon*, 221, USPQ 1125, 1127 (1984) stated:

The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. (Case citations.)

Thus, without a motivational teaching in the art to combine the known ingredients in the manner specifically claimed, the Applicant respectfully submits that the Examiner has not satisfied her burden of establishing a prima facie case of obviousness and the burden

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should not be automatically shifted to the Applicant to show some unexpected results in order to avoid such a rejection.

It is respectfully submitted that it is improper to combine the prior art, which is not equally concerned with the problems or arrive at the novel solution of the invention, by simply piecing together ingredients from various references. As a whole, Ringe is not concerned with a high protein product. As a whole, Sander is not concerned with a high multi-fiber product. Simply stated, neither Ringe nor Sander suggest making a combination high multi-fiber and high protein cooked dough product, particularly in further consideration of the ranges and ratios recited, and it is not permissible for the suggestion of the combination to simply come from the Examiner for a proper prima facie case of obviousness. As the PTO has to establish a prima facie case of obviousness and "obvious can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentives supporting the combination" *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984) and *Ray Geiger*, 815 F.2d 686 (Fed. Cir. 1987), the rejections are seen to be improper

In a similar manner, Van Lengerich et al. is not concerned with a high insoluble fiber, high soluble fiber and high plant protein product such that the mere fact that Van Lengerich et al. teaches to make a cereal dough with inulin does not detract from the inventiveness of the combination set forth in this application. Based on the above, it is respectfully requested that the prior art rejections be withdrawn, the claims allowed and the application passed to issue.

Respectfully submitted,

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